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Endologix, Inc. (ELGX)

BMO Prescription for Success Healthcare Conference

CORPORATE PARTICIPANTS

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

OTHER PARTICIPANTS

Joanne K. Wuensch
Analyst, BMO Capital Markets (United States)

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

MANAGEMENT DISCUSSION SECTION

Joanne K. Wuensch
Analyst, BMO Capital Markets (United States)

We are heading towards our next presentation and this is for Endologix. And we have Vaseem Mahboob with us, and we have Matt Thompson with us today. And welcome.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

Well, thank you for having us.

QUESTION AND ANSWER SECTION

Joanne K. Wuensch
Analyst, BMO Capital Markets (United States)

Q

The company has gone through a lot in the last 12 months or something. Walk me through sort of what you think is the recovery path, what you've accomplished in the last 12 months and what's the recovery path from here?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

So, as I was actually processing it, I remembered that we were here exactly around the same time, Joanne, last year.

Joanne K. Wuensch
Analyst, BMO Capital Markets (United States)

Q

It was.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

And we had the meet and greet for John Onopchenko, who's our new CEO, and he laid out five key focus areas in the transformation of the company. And albeit, at that time, it was an early thinking before we kind of presented an update at the Investor Day. But in those five things that John talked about, the first one was focusing on the markets, focusing on our products, our clinical pipeline, our expenses and then, lastly, around the culture, right.

So, on the market side, we look at it today. We've gone from 40 some countries down to just slightly over 20 countries. Our commercial footprint is more predictable, more durable, more scalable and we have reduced our cash consumption OUS, so which is what we were trying to strive for.

On the product side, we rationalized our NPI footprint. We really focused on the key value drivers of the company and the value driver for the company remains the Next Gen EVAS platform, which is funded for some of the other programs like the thoracic program that we are working with our partner JLL in Japan. We shelved that, but wanted to focus the company on next gen. So that was the second big change.

On the clinical side, we continue to make progress on Alto, getting that to market here in the second half of the year, continue to finish enrollment on EVAS2 and then, eventually, getting approval for the ChEVAS IDE with the FDA this year. So we remain on track to do those things.

The fourth area was really looking at our expenses and, again, it's a huge transformation for the company. We rightsized our commercial footprint in the U.S. We went from 110 salespeople down to about 90, which by the way was the right number. It's not that we were trying to rip cost out of the business for just taking cost out. If you remember, we had built out the U.S. commercial footprint ahead of the Nellix launch, which is now delayed. So we rightsized that back to the capacity that we needed to grow, especially with Alto coming.

We also restructured our OUS footprint. We took our commercial head count down in Europe by 40%. We lowered our operating expenses from $165 million last year to our guidance for this year is $130 million to $140 million. We really took a pretty significant chunk of cost out of the business really to lower our cash consumption

and we feel really good about that, because if you look at where we were tracking to Q4, we have bent the curve on those expenses and feel pretty good about the guidance this year.

Lastly, as John told you last year, if you're not satisfied with the results, you can be satisfied with the culture. We have made significant changes and it's a brand new management team and Matt and I were joking here. He and I are the only two people left from the old management team.

Joanne K. Wuensch
Analyst, BMO Capital Markets (United States)

Q

Congratulations.

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

Thanks very much.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

And so, we brought in people like Jeff Fecho, who was a Section 16 officer at St. Jude to be the Chief Quality Officer. We have Jeff Brown as the new Chief Operating Officer. We have Elisa Hebb, who runs our regulatory; our VP of HR, Reyna Fernandez, that started at the beginning of this year. So, again, it's a pretty significant change from management team perspective. So, again, you asked the question what's happened in the last four months, a lot has happened. But I think the great news here is that it's a different company with a better accountability, culture, with the high say/do and we continue to move in that direction.

Joanne K. Wuensch
Analyst, BMO Capital Markets (United States)

Q

And what am I looking forward to in the next 12 months?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Well, I mean, again what we have messaged as the catalyst for the company, again, in the second half of the year, we got Alto coming, which Matt can talk about here in a second. We'll get approval for the ChEVAS IDE here in the second half of the year. We have had 10 straight quarters of negative declines. And on the heels of a stabilizing U.S. AFX business, sequential growth on Ovation as we put out in the framework at Investor Day, we feel that we can return this business back to growth and I think that's a pretty significant change for the company.

Joanne K. Wuensch
Analyst, BMO Capital Markets (United States)

Q

And when you think about business back to growth, are we a mid-single digit grower or high-single digit grower over time?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

So, when we – at the Investor Day on October 2 last year, we put out like the three-phased approach to the company. We said 2019 and 2018 were all about kind of building the foundation, regaining confidence of our

employees, our physicians and our investors having the kind of culture of high say/do, and getting some of the things that I just talked about, getting them done.

In the second phase of the transformation, we also put out back in the October Investor Day that we expect in the second phase to grow 1 point above market, again, and if you know, the AAA market has grown mid-single digit, so again, a modest growth next year. So I'm not going to talk about guidance for 2020, but at least as a framework, all of that has been publicly spoken about. So we intend to kind of go down that path and make sure that we hit some of the milestones to get to those timelines.

Joanne K. Wuensch
Analyst, BMO Capital Markets (United States)

Q

I think Matt Henriksson may have some questions...

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

[ph] Sure, yeah (00:05:41).

Joanne K. Wuensch
Analyst, BMO Capital Markets (United States)

Q

Together, Matt, on Ovation Alto. Matt?

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

Yes. So continuing with the theme of Ovation Alto coming out in the second half of the year...

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Yeah.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

...walk us through the benefits of a polymer-based device versus the traditional stent graft and as well as the benefits between the first-generation Ovation device?

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

Sure. Let me do the kind of polymer-based in EVAR first. So, if you go to most of the big academic meetings now in EVAR, the conversation with physicians has really changed from the benefits that EVAR has in the very short term to the problems that traditional EVAR is having in the long term. So if you look the randomized controlled trials that are often the basis for decision-making, what we see now is that once the EVAR gets out past about five years, it becomes an issue with regard to long-term durability.

And we know that patients are living longer and longer with half the patients who've had an EVAR still alive at nine years. So the durability issues that we see with conventional EVAR platforms, which are the self-expanding, modular, oversized stents, they're becoming an issue at five years and what we think is that a polymer-based

solution that's very anatomically adaptive, it doesn't press out and create outward force on the neck. That is likely to result in better durability than we see with the self-expanding stents.

So we have preliminary evidence to support that statement from our ENCORE registry, which is a 1,300 patient registry, and when we look at the behavior of the largest size Ovation graft and it's the large sized grafts that always have the worst outcomes. We see a very different pattern with polymer-based technology as opposed to self-expanding stents. So that's really our look into the future is one of enhanced durability with polymer-based platforms.

If I then turn to what's different to Alto with regard to the other Ovation platforms then it's twofold really. One is the applicability of the endograft is going to be a lot higher with the ability to treat 80% of the noncomplex market, about 25% of the short neck complex market. The more the docs are within the anatomical indications for use of the product, the better results. And so, we think that enhanced applicability will translate to more patients being treated within IFU and better results.

And then, the real positive that we see with Alto is that it's essentially designed to overcome some of the acute hurdles that doctors describe with the current Ovation platform in that it's slightly more difficult to use than a conventional bifurcated graft. It's slightly more difficult to size. The procedure takes a little bit longer and all of those features really have been designed out of Alto so that it's going to be technically a much easier procedure. It's going to be much easier to size the endograft and that we believe will result into acute outcomes. So it's a significant advance for us.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

Okay. And then with the ELEVATE data, which is the clinical trial for Alto...

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

Yeah.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

...when would we expect to see data for it and what data points should we pay attention to?

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

Okay. So, important to realize, this is a confirmatory trial. So it's a small sample size; it's only 75 patients that we're reporting to the FDA so very difficult to draw any big conclusions from such a small data set. As to when you are going to expect to see it, that will be immediately after Alto approval, which as Vaseem said, we're still predicting sometime in the latter half of this year.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Q

Okay.

Joanne K. Wuensch
Analyst, BMO Capital Markets (United States)

Q

Back to me. Earlier this month, you got CE Mark approval reinstated for Nellix. How should we interpret that?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Positive.

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

Yeah. Positively I think so I mean...

Joanne K. Wuensch
Analyst, BMO Capital Markets (United States)

Q

[indiscernible] (00:10:02) So it was good.

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

[ph] Let's see (00:10:04).

Joanne K. Wuensch
Analyst, BMO Capital Markets (United States)

Q

It's a good thing. All right. So let me – let's take this a different way. Does that change – does that mean you have a better relationship with the CE Mark authority? Does that change your view of the Nellix opportunity as you have seen it?

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

So if I just kind of rehearse what happened at...

Joanne K. Wuensch
Analyst, BMO Capital Markets (United States)

Q

Yeah.

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

A

...the latter part of the year. So we voluntarily took Nellix out of the European market because despite three Field Safety Notifications, we just couldn't constrain the use to the on-label patient population. And what we learnt from the EVAS1 trial in the U.S. and subsequently in the EVAS2 trial is that with Nellix, it's a new therapy. It's not EVAR and therefore, the principles of EVAR are not directly applicable. So what we know with Nellix is when you're on-label with a good procedure, your results are really very good indeed. When you go off-label, however, the results deteriorate rapidly. And so, therefore, we got to constrain Nellix use to being within the anatomical indications for use.

So, not being able to do that despite three FSNs and then we took it out of circulation, that resulted not unreasonably in GMED saying, well, if you're unsure, we're unsure. We'll suspend the [indiscernible] (00:11:29). But we gave them our up-to-date clinical data. We gave them a plan for how we were going to constrain the use to on-label, and that's what directly allowed them to reinstate the CE Mark. So it's a positive validation of our data.

So we think the data are very good for Nellix when used on-label with the good procedure and GMED, our Notified Body, agreed with that with their independent review of the data. So it's positive. It's further good news for Nellix. It energizes the EVAS2 trial in the United States and we have a clear pathway back to selling Nellix in Europe, but it's going to be, as we said in our FSN, within the confines of the clinical protocol constraining it to on-label use.

Joanne K. Wuensch
Analyst, BMO Capital Markets (United States)
Q

If the two of you were the only survivors, [ph] I'm going to make (00:12:25)...

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.
A

Sure.

Joanne K. Wuensch
Analyst, BMO Capital Markets (United States)
Q

... [ph] some television show of this, (00:12:26) did also the reimbursement and the regulatory people change?

Matthew Thompson
Chief Medical Officer, Endologix, Inc.
A

Well, obviously, so I look after regulatory, Vaseem can talk about reimbursement, our core teams are actually still intact. So, for me, the folks who are dealing with the Nellix PMA from senior director down to project managers are all intact. We replaced the head of regulatory affairs. Elisa Hebb now looks after both Clinical and Regulatory Affairs. But the structure of the team remains intact and the people who deal with the FDA on a day-by-day basis still remain the same.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.
A

I think the same is true for most of the functions.

Joanne K. Wuensch
Analyst, BMO Capital Markets (United States)
Q

Okay. And does Nellix ever see the light of day here in the U.S. and does it matter?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.
A

Well, absolutely. I mean, we have a path where, as Matt said, I think the big positive here is that impact to the EVAS2 IDE in a positive way. We're still on track to finish enrollment here in the second half of the year. And if you follow those patients for a year, you have a path to getting Nellix in the U.S. market in 2021. Now having said that, I think the one significant point I want you guys to walk away with is when we showed the competent

authority in Europe the data of EVAS2 were the same patients that were in EVAS1, at two years, the data was pretty compelling for them to reinstate the CE Mark.

Joanne K. Wuensch
Analyst, BMO Capital Markets (United States)

Q

Yeah.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

So from that perspective, listen, when you look at the narrowed IFU, it's still 40% of the infrarenal market. So it can still be a very significant opportunity, but as we have said publicly, the real price is going to be ChEVAS, and I think the pathway to ChEVAS is going to be through the EVAS2 IDE. So, overall, I think Nellix is still a very compelling and attractive opportunity for the company to pursue.

Joanne K. Wuensch
Analyst, BMO Capital Markets (United States)

Q

What do you want to make sure, other than that, everybody here hears?

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

A

Well, I think the big message for us continues to be that we are a company in transition. I think we have made very significant changes to improve not only the risk profile of the company, but also the capability of the company. We are on track to get away from the declines that we have seen in our top line and resume a growth profile as we would want to be, and I think with this pipeline and some of the catalysts coming here in the second half of the year and also the next couple of years, Endologix remains to be the most compelling opportunity with the AAA market. So again, still too early to throw confetti, but I think we've made significant progress and that we'll continue to do so.

Joanne K. Wuensch
Analyst, BMO Capital Markets (United States)

Vaseem and Matt, thank you so much for joining us today.

Matthew Thompson
Chief Medical Officer, Endologix, Inc.

Sure.

Vaseem Mahboob
Chief Financial Officer, Endologix, Inc.

Well, thank you for the opportunity.

Matthew Henriksson
Analyst, BMO Capital Markets (United States)

Thanks, Matt.